

WHAT IS CLAIMED IS:

5at 1 (1) A pharmaceutical composition comprising an anticancer drug as active ingredient
2 dissolved in a carrier system comprising at least one hydrophobic component, a hydrophilic
3 component and at least one surfactant, wherein the hydrophobic component is selected from
4 triglycerides, diglycerides, monoglycerides, free fatty acids, and fatty acid esters and
5 derivatives thereof, individually or in combination and wherein the hydrophilic component is a
6 hydroxyalkane, a dihydroxyalkane, a polyethylene glycol having an average molecular weight
7 of less than or equal to 1000 or mixtures thereof.

1 2 (2) A pharmaceutical composition consisting essentially of a taxane dissolved in a
2 carrier system composed of a surfactant, a hydrophobic component comprising a triglyceride,
3 diglyceride, monoglyceride, free fatty acid, fatty acid ester or mixtures thereof and hydrophilic
4 phase comprising a hydroxyalkane, a dihydroxyalkane, polyethylene glycol having a molecular
5 weight of at most 1000.

1 3. The composition of claim 1 or claim 2 wherein the hydrophobic component is a fatty
2 acid ester of a hydroxyalkane, a fatty acid ester of a dihydroxyalkane, a fatty acid mono-, di- or
3 triglyceride or a transesterification product of a vegetable oil with a glycerol.

1 4. The composition of claim 1 or claim 2 wherein the hydrophilic component is 1,2-
2 propylene glycol, ethanol, a polyethylene glycol or mixtures thereof.

1 5. The composition of claim 1 or claim 2 wherein at least one surfactant is non-ionic.

1 6. The composition of claim 1 or claim 2 further including an inhibitor of P-
2 glycoprotein transport system or an inhibitor of P450 enzymes.

1 7. The composition of claim 6 wherein the inhibitor is grapefruit extract or a
2 component thereof.

1 2 (8) A storage-stable self-emulsifying preconcentrate of an anticancer drug in a
3 microemulsion composed of:

5at 4 10 to 80% w/w of a hydrophobic component of at least one triglyceride, diglyceride,
5 monoglyceride, free fatty acid, fatty acid ester, fish oil, vegetable oil or mixtures thereof; 20 to
6 80% w/w of surfactant phase comprising at least one non-ionic surfactant,
7 0-35% w/w diethylene glycol monoethylether, and
8 0 to 40% w/w of at least one hydrophilic component selected from a hydroxyalkane,

9 dihydroxyalkane, a polyethylene glycol having an average molecular weight of at most 1000,
10 and mixtures thereof

11 wherein said preconcentrate, when mixed with an aqueous medium, gives an average
12 particle size of at most 10 microns.

1 9. The self-emulsifying preconcentrate of claim 8 containing from 15 to 75% w/w
2 hydrophobic component.

1 10. The self-emulsifying preconcentrate of claim 8 containing from 20 to 80% w/w
2 surfactant.

1 11. The self-emulsifying preconcentrate of claim 8 containing up to 30% w/w
2 hydrophilic component.

1 12. A storage-stable, self-emulsifying, clear, liquid preconcentrate of at least one
2 taxane ^{in a composition} consisting essentially of:

3 10 to 80% w/w of a hydrophobic component of at least one triglyceride, diglyceride,
4 monoglyceride, free fatty acid, fatty acid ester, fish oil, vegetable oil or mixtures thereof;

5 20 to 80% w/w of surfactant phase comprising at least one non-ionic surfactant, and

6 up to 40% w/w of at least one hydrophilic component selected from a hydroxy alkane, a
7 dihydroxyalkane, a polyethylene glycol having an average molecular weight of at most 1000,
8 and mixtures thereof

9 wherein said preconcentrate, when mixed with an aqueous medium, gives an average
10 particle size of at most 10 microns, or which upon oral administration forms *in situ* a
11 microemulsion in the gastrointestinal tract.

1 13. The liquid preconcentrate of claim 12 wherein the hydrophilic component is
2 selected from 1,2-propylene glycol, ethanol, polyethylene glycol having an average molecular
3 weight of less than or equal to 1000 and combinations thereof.

1 14. The liquid preconcentrate of claim 13 wherein the hydrophilic component is
2 present and is a mixture of 1,2-propylene glycol and ethanol.

1 15. The liquid preconcentrate of claim 12 containing up to 30% w/w hydrophilic
2 component.

1 16. The liquid preconcentrate of claim 12 wherein the hydrophobic component is a
2 fatty acid ester of a hydroxyalkane, a fatty acid ester of a dihydroxyalkane, a fatty-acid mono-,
3 di- or tri-glyceride or a transesterification product of a vegetable oil with a glycol.

1 17. An orally administrable pharmaceutical composition consisting essentially of the
2 preconcentrate of claim 12 in a pharmaceutically acceptable carrier or diluent.

1 18. A parenterally injectable pharmaceutical composition consisting essentially of the
2 preconcentrate of claim 12 in a pharmaceutically acceptable diluent.

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3 19. A method of orally or parenterally administering an anticancer drug to a subject in
4 need of same comprising storage-stable, self-emulsifying preconcentrate of a solubilized
5 anticancer drug composed of:

6 10 to 80% w/w of a hydrophobic component of at least one triglyceride, diglyceride,
7 monoglyceride, free fatty acid, fatty acid ester, fish oil, vegetable oil and mixtures thereof;
8 20 to 80% w/w of surfactant phase comprising at least one non-ionic surfactant, and
9 up to 40% w/w of at least one hydrophilic component selected from a hydroxy alkane, a
10 dihydroxy alkane, a polyethylene glycol having an average molecular weight of at most 1000,
11 and mixtures thereof

12 wherein said preconcentrate, when mixed with an aqueous medium, gives an average
13 particle size of at most 10 microns.

1 20. A method of orally administering a self-emulsifying preconcentrate of claim 12
2 comprising a taxane solubilized in a stable, self-emulsifying system which self-disperses in
3 water, simulated intestinal, or simulated gastric fluid to yield a homogeneous phase with a
4 particle size of below 10 microns.

5 21. A method of enhancing the oral bioavailability of a taxane comprising solubilizing
6 a taxane in a stable, self-emulsifying ^{non aqueous} system which upon administration forms *in situ* a
7 microemulsion in the gastrointestinal tract.

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